

Re: Libby RfC - SAB request Fw: Request For Additional Information

Bob Benson to: Krista Christensen

01/24/2012 01:36 PM

From: Bob Benson/R8/USEPA/US
To: Krista Christensen/DC/USEPA/US
Cc: Danielle DeVoney/DC/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA

Do not send the spreadsheets. UC has asked that we delete some of the columns that will allow identification of individuals.

Krista Christensen---01/24/2012 01:26:45 PM---I think so--I hope everyone's had a chance to look and comment if desired. I'm referring to the wor

From: Krista Christensen/DC/USEPA/US
To: Danielle DeVoney/DC/USEPA/US@EPA
Cc: Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/24/2012 01:26 PM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

I think so--I hope everyone's had a chance to look and comment if desired. I'm referring to the word document here...not sure if we've reached consensus on the excel dataset file, but perhaps both versions can be sent to management with the understanding that they won't go any further until the UC folks confirm they are okay with the contents.

Krista

Danielle DeVoney---01/24/2012 02:05:34 PM---Krista - Is this ready to go forward for management review and then transmittal?

From: Danielle DeVoney/DC/USEPA/US
To: Krista Christensen/DC/USEPA/US@EPA
Cc: Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/24/2012 02:05 PM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

Krista -

Is this ready to go forward for management review and then transmittal?

Danielle

Danielle DeVoney, PhD, DABT, PE

National Center for Environmental Assessment
USEPA Office of Research and Development
1200 Pennsylvania Ave., NW (8623P)
Washington, DC 20460
703.347.8558
FAX: 703.347.8692

Krista Christensen---01/24/2012 12:37:12 PM---Now featuring comments from Leonid, Danielle and Tom: note that the only changes in this round are t

From: Krista Christensen/DC/USEPA/US
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Cc: Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/24/2012 12:37 PM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

Now featuring comments from Leonid, Danielle and Tom:

[attachment "DataRequest_KYC_24Jan2012.docx" deleted by Danielle DeVoney/DC/USEPA/US]

note that the only changes in this round are to the footnotes (all tables), and the column header of table 1.
Sorry for flooding everyone's inbox today!

Krista

Danielle DeVoney---01/24/2012 11:32:12 AM---Krista - Hi - Great job!

From: Danielle DeVoney/DC/USEPA/US
To: Krista Christensen/DC/USEPA/US@EPA
Cc: Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/24/2012 11:32 AM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

Krista -

Hi - Great job!

A few comments:

1) In the first table you provide with demographic characteristics. Although we have consistently used the term full cohort. This might be best understood really as a combined cohort, as we combined the data from both reports and removed duplicates. For the subcohort we describe what data was included. I would suggest a similar descriptor be added for the full cohort.

" All individuals examined either in 1980, or 2002-05, with the most recent x-ray result."

2) I would suggest the footnote on the first table be shortened. The reading of x-rays is somewhat subjective. A smaller lesion of the visceral pleura would be graded as LPT, until it was large enough and had

CPA involvement to be called DPT. So statistically some of our "LPTs" may be small visceral lesions. Also any DPT, must have been an LPT at some point in time. However, an individual could have both parietal plaques and fibrosis of the visceral pleura (Two different types of lesions) and if the visceral lesions is large enough to be considered DPT, they would be graded with both LPT (for the parietal plaques) and DPT (for the visceral lesion):

*One individual with diffuse pleural thickening was removed from the analytic dataset, [as this is a more severe endpoint than LPT.](#) ~~since they were not 'at risk' for developing the outcome of interest (LPT)~~

This is a point where the statistical language and the biological are a bit at odds. The individual must have had a lesion which would have been graded as LPT at some point - so they were a positive in that sense. However, they are not without risk of a future parietal lesion, and therefore a different form of LPT in the future.

3) Also on table 1: I thought there was another individual who was excluded from analysis. There was a 1980 x-ray showing pleural lesions after only 6 months of employment, and that this was removed from analysis due to implausibility. Is this included?

4) suggest adding a page break after the first table.

Danielle DeVoney, PhD, DABT, PE
National Center for Environmental Assessment
USEPA Office of Research and Development
1200 Pennsylvania Ave., NW (8623P)
Washington, DC 20460
703.347.8558
FAX: 703.347.8692

Krista Christensen---01/24/2012 10:47:59 AM---Hi all- In reference to request #2-4 below, here is a word document with the requested information..

From: Krista Christensen/DC/USEPA/US
To: Danielle DeVoney/DC/USEPA/US@EPA
Cc: Bob Benson/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
Date: 01/24/2012 10:47 AM
Subject: Re: Libby RfC - SAB request Fw: Request For Additional Information

Hi all-

In reference to request #2-4 below, here is a word document with the requested information...it is formatted similarly to tables in the document but please weigh in on changes needed for SAB/public posting.

In regards to request #1, the first table in the doc has demographic characteristics of the full and subcohort, similar to the table in the cancer section of ch 5...I guess it's still up in the air what exactly is needed, but hopefully this will meet the requestor's need.

Thanks,
Krista

[attachment "DataRequest_KYC_24Jan2012.docx" deleted by Danielle DeVoney/DC/USEPA/US]

Danielle DeVoney---01/23/2012 06:33:22 PM---Hi all, Please see the request by SAB below for both raw data and modeling results to support the Rf

From: Danielle DeVoney/DC/USEPA/US
To: Leonid Kopylev/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Bob Benson/R8/USEPA/US@EPA
Cc: Deborah McKean/R8/USEPA/US@EPA, David Berry/R8/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA
Date: 01/23/2012 06:33 PM
Subject: Libby RfC - SAB request Fw: Request For Additional Information

Hi all,

Please see the request by SAB below for both raw data and modeling results to support the RfC. It seems like we could fulfill the request for our modeling results directly, but may need to coordinate with Dr. Lockey for the data requests.

A) I believe NCEA would be the lead for items 2,3 and 4 below corresponding to more information on the model results provided in tables E-1, E-2, E-3 E-4 and E-5. Can we provide this information as requested? How long will it take to prepare for transmittal to the SAB? (Remembering what we provide will be available to the public - so we need to format it for clarity.)

Krista - can you be the lead on this?

B) For Item 1 below "More basic data description for the primary subset and full cohort used for analysis": I interpret this as more than a verbal description - and it might be useful to provide the actual data input file to the model in addition to a brief description (taken from the text?). If we do this, we need to check with Univ. of Cincinnati regarding sharing these data.

For each analysis (full and subcohort) can we provide a spreadsheet of the relevant data input to our modeling? (removing personal identifiers)

If we need clearance from Univ of Cincinnati to provide these to the SAB - should we send them the files for review prior to sending to the SAB?

C) On the final item - it would seem we need to contact Univ. of Cincinnati for permission to forward the complete data file (minus identifiers.)

Bob - can you take the lead on this? Should we ask Dr. Lockey if they would like to provide the clean file so they have direct control over what is released?

Bob - Do you know what our contract with Univ. of Cincinnati says with respect to our ability to share the raw data they provided?

It is possible we could receive similar requests for additional information on the cancer models.

Danielle

Danielle DeVoney, PhD, DABT, PE
National Center for Environmental Assessment
USEPA Office of Research and Development
1200 Pennsylvania Ave., NW (8623P)
Washington, DC 20460
703.347.8558
FAX: 703.347.8692

----- Forwarded by Danielle DeVoney/DC/USEPA/US on 01/23/2012 06:02 PM -----

From: Diana-M Wong/DC/USEPA/US
To: Danielle DeVoney/DC/USEPA/US@EPA, Bob Benson/R8/USEPA/US@EPA
Cc: Bob Sonawane/DC/USEPA/US@EPA, Deborah McKean/R8/USEPA/US@EPA
Date: 01/23/2012 05:35 PM
Subject: Request For Additional Information

Dear All,

A SAB Panel member is requesting for more information on the following for evaluation of EPA's analysis on estimating the RfC:

- 1) *More basic data description for the primary subset and full cohort used for analysis.
- 2) *Estimates of the regression coefficient and its SE for exposure in all models (refer to Table E-1).
- 3) *All parameter estimates in the models in Table E-2. (Specifically, all models with ln(CHEEC) as exposure at a 10 year lag. That would be the logistic, probit, 3-parameter logistic, Dichotomous Hill, and Michaelis-Menten).
- 4) *All coefficient estimates for the model assessing smoking (refer to Table E-4, also E-5)
- 5) *Raw data file used in the analysis

Please make this information as soon as you can. Thanks.

Diana

Diana Wong, Ph. D., DABT
Toxicologist and Designated Federal Officer
USEPA
Science Advisory Board Staff Office
MC: 1400R
1200 Pennsylvania Ave, N.W.
Washington, DC 20460

Phone:(202) 564-2049